K093777

SECTION 5 – 510(K) SUMMARY

Axis Surgical Technologies, Inc.

MAR - 2 2010

Submitter / Holder:
Axis Surgical Technologies, Inc.
325 E. Middlefield Road
Mountain View, CA 94043

Contact Person:
James Farnworth
RA/QA
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Date prepared:
December 1, 2009

Device Information:

Trade name:	C-MOR Visualization System
Common name:	Arthroscope
Classification name:	Arthroscope
Panel:	Orthopedic
Product Code:	HRX
Device Class:	Class 2

Predicate Devices:

510(k) Number	Trade Name	Manufacturer
K082293	Surgview integrated visualization system	Biovision Technologies, LLC
K043395	S&N Video Arthroscope	Smith & Nephew
K072879	InnerVue Diagnostic Scope System	Biomet

Intended Use / Indications for Use:
The Axis Surgical Technologies C-MOR Visualization Device is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

Device Description:
The C-MOR Visualization Device is a battery operated, portable, visualization device including an integrated LCD monitor and probe. The C-MOR Visualization Device is easily handled in one hand and includes a user interface, electronics, user controls, and LED light source. The LCD monitor displays real-time images from the probe and is flexibly mounted on the handle – allowing adjustment of the LCD viewing angle. The probe extends from the handle as a rigid shaft seating a CMOS camera and fiber optic lighting located at the distal tip.

The overall length of the C-MOR Device 342 mm (approx. 13.5 inches); including the probe portion and handle. The probe length, extending from the handle, is 150 mm (approx. 6 inches). The entire unit weighs less than 300 grams (approx. 0.67 lbs.).

Substantial Equivalence:
The C-MOR Visualization Device has the same indications and intended use as the predicate devices. The subject and predicate devices utilize the same basic technology and the same operating principles. Performance data supporting the claim of substantial equivalence is included in the body of the premarket notification.

Performance:
The C-MOR Visualization Device complies with the international standards for EMC, Medical Device Electrical Safety and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Axis Surgical Technologies, Inc.
% Mr. James Farnworth
Director, RA/QA
325 E. Middlefield Road
Mountain View, California 94043

MAR - 2 2010

Re: K093717
Trade/Device Name: C-MOR Visualization System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: January 28, 2010
Received: January 29, 2010

Dear Mr. Farnworth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

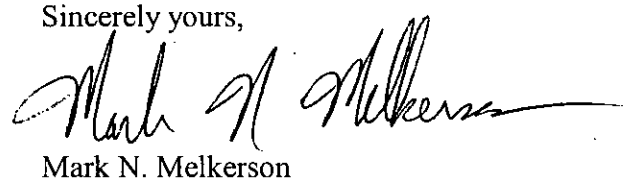
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K093717

Device Name: C-MOR Visualization System

Indications For Use:

The Axis Surgical Technologies C-MOR Visualization Device is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination and visualization of an interior cavity of the body through either a natural or surgical opening.

Prescription Use ___X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices